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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/589,483	06/07/2000	Vikas P. Sukhatme	1440.1031-010	1320

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EXAMINER	
KATCHEVES, KONSTANTINA T	

ART UNIT	PAPER NUMBER
1636	24

DATE MAILED: 03/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/589,483	SUKHATME, VIKAS P.	
	Examiner	Art Unit	
	Konstantina Katcheves	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 November 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6,8,9,14-17,22,23,25 and 26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6,8,9,14-17,22,23,25 and 26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☐ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4)☐ Interview Summary (PTO-413) Paper No(s). _____ .
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other: .

DETAILED ACTION

Claims 1-4, 6, 8, 9, 14-17, 22, 23, 25 and 26 are pending in the present application. This Office Action is in reply to Applicant's Amendment and Arguments in Paper No. 18, filed 7 November 2002. In Paper No. 18, Applicant presented amendments to claims 36 and 38. Applicant should note that those claims were cancelled in Paper No. 14, filed 15 February 2002. The amendments to claims 36 and 38 submitted in Paper No. 18 have not been entered and have not been considered.

Continued Prosecution Application

The request filed on 7 January 2003 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/589483 is acceptable and a CPA has been established. An action on the CPA follows.

Response to Amendment

Claims 1-4, 6, 8, 9, 14-17, 22, 23, 25 and 26 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey that the inventors had possession of the claimed invention for the reasons of record set forth in the office action mailed 2 August 2002.

Response to Arguments

Claims 1-4, 6, 8, 9, 14-17, 22, 23, 25 and 26 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a

way as to reasonably convey that the inventors had possession of the claimed invention for the reasons of record set forth in the office action mailed 2 August 2002. Applicant's arguments filed 25 February 2002 have been fully considered but they are not persuasive.

The written description requirement is established by 35 U.S.C. 112, first paragraph which states that the: "*specification* shall contain a written description of the invention. . .[emphasis added]." The written description requirement has been well established and characterized in the case law. According the written description requirement, a specification must convey to one of skill in the art that "as of the filing date sought, [the inventor] was in possession of the invention." See *Vas Cath v. Mahurkar* 935 F.2d 1555, 1560 19 USPQ2d 1111, 1117 (Fed. Cir. 1991). Applicant may show that he was in "possession" of the invention claimed by describing the invention with all of its claimed limitations "by such descriptive means as words, structures, figures, diagrams, formulas, etc., that fully set forth the claimed invention." See *Lockwood v. American Airlines Inc.* 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997).

As discussed in the office action mailed 2 August 2001, Applicant's invention is drawn to a method of making a restin protein or a "biologically active mutant, fragment or fusion protein thereof." The claimed biologically active mutants, fragments, derivatives or fusion proteins of restin have not been adequately described in the specification such that one of skill in the art would reasonably conclude that Applicant was in possession of such a broad genus of compounds at the time the invention was made.

Applicant expresses concern that the present rejection under the written description requirement is inappropriate because the claims currently under consideration are all method

claims not compositions of matter claims. The written description requirement is not limited to composition of matter claims. Possession is an issue that relates to methods as well as compositions. In the present application, the mutants, fragments and fusion proteins of restin are the crux of the invention. Because Applicant does not have possession of such a broad genus, they do not have possession of the invention.

Applicant has expressed confusion regarding the present rejection. The rationale for the present rejection will be again explained in hopes of clarifying any confusion for Applicant. Applicant relies upon the disclosure of apomigren, which is a fragment of full length restin comprising about the last 85 amino acid residues of restin. Applicant also relies upon the disclosure of methods of cloning and assaying for apomigren provided. Applicant has adequately described apomigren and possibly fragments comprising the 85 amino acids of apomigren. The claims, however, read on sequences that include the first 97 amino acids of restin, which may or may not include the 85 amino acids of apomigren. Additionally, the claims read on mutants and fragments of restin, including mutations at any position in the length of the sequence. The biological activity of these sequences must be maintained. Applicant has failed to teach which parts of the full length sequence of restin are required to maintain this biological activity. Thus, an extremely large number of mutations, fragments and fragments comprising mutations are possible such that one of skill in the art would not reasonably accept on its face that Applicant had possession of all mutants, fragments and fusion proteins of restin. Applicant has failed to provide any teaching, except apomigren, as to structural features required for the activity of restin. The claims, however, read on sequences that can comprise any fragment and mutants of restin, which include possible fragments and mutations in the apomigren domain.

Applicant's disclosure of apomigren clearly does not describe any biologically active mutants, fragments, derivatives or fusion proteins of restin.

Applicant argues that the claims require an essential or critical feature, antiangiogenic activity, such that the written description requirement is satisfied. It is still the examiners position, that Applicant has merely described a way to screen or identify these mutants, fragments, or fusion. Applicant still does not have possession of this very broad genus of proteins.

Again, Applicant should be noted that the scope of the claims is well beyond the scope of apomigren. Applicant has done little more than disclose apomigren and send the skilled artisan on a hunt for mutants, fragments, derivatives or fusion proteins of apomigren having anti-angiogenic activity. The guidelines as set forth in MPEP 2163 (I)(A) state:

> A biomolecule described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method for obtaining the claimed sequence.

By stating that the "activity is somewhere within the region making up the apomigren sequence," Applicant admits that no known correlation exists between the mutants, fragments and variants of the sequence claimed and the anti-angiogenic activity. The court in *Regents of the University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 43 USPQ2d 1398 also address this issue explicitly stating:

> A generic statement . . . without more, is not an adequate written description of the genus because it does not distinguish the claimed genus from others, except by function. . . .It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus.

Applicant has taught apomigren and an assay for anti-angiogenic activity. Therefore, even though Applicant teaches a sequence and a method for assaying for anti-angiogenic activity, it is still insufficient to describe the broad genus claimed. Applicant must show some common structural feature of either the apomigren sequence or the entire restin sequence that would allow one of skill in the art to visualize the broad genus claimed.

Applicant argues that the set of total number fragments of SEQ ID NO:10 can be set forth with no more than a pencil. This is may be true, not because as Applicant asserts that SEQ ID NO:10 is drawn to full length restin; rather because SEQ ID NO:10 comprises a 26mer oligonucleotide. With regard to this argument as it applies to full length restin, restin is a protein comprising 181 amino acids or encoded by approximately 543 nucleotides. Given the length of the sequence and the requirement for antiangiogenic activity, Applicant does not have possession of any mutants, fragments or fusions proteins for the reasons set forth above.

Conclusion

This is a continuation of applicant's earlier Application No. 09/589483. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konstantina Katcheves whose telephone number is (703) 305-1999. The examiner can normally be reached on Monday through Friday 7:30 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel, Ph.D. can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-7939 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-3388.

Konstantina Katcheves
March 24, 2003

REMY YUCEL, PH.D
SUPERVISORY PATENT EXAMINER
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